



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0245; FRL-9352-4]

RIN 2070-ZA16

Methyl bromide; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of methyl bromide in or on cotton, undelinted seed under the Federal Food, Drug, and Cosmetic Act (FFDCA) because there is a need for imported undelinted cottonseed for use as additional feed for dairy cattle in the United States.

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0245; FRL-9352-4, is available either electronically through <http://www.regulations.gov> or in hard copy at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open

from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Kimberly Nesci, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8059; email address: nesci.kimberly@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding

the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0245 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any Confidential Business Information (CBI) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request,

identified by docket ID number EPA-HQ-OPP-2012-0245, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Background

In the **Federal Register** of April 6, 2012 (77 FR 20752) (FRL-9345-1), EPA issued a proposed rule pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3). The rule proposed that 40 CFR 180.124 be created to establish a tolerance for residues of methyl bromide, including metabolites and degradates in or on cotton, undelinted seed at 150 parts per million (ppm). EPA issued a proposed rule that explained the basis for EPA's conclusion that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from exposure to methyl bromide on cottonseed because there will be no human dietary exposure to methyl bromide from the

use of methyl bromide to fumigate cottonseed. The proposal established a 60-day public comment period. Comments were received in response to the proposed rule. EPA's response to these comments is discussed in Unit III.

III. Response to Comments

Comments were received in response to the proposed rule from a large dairy producer trade association, from a dairy industry expert, and from two other individuals. The comments from the dairy producer trade association and from the dairy industry expert are in support of the establishment of a tolerance for methyl bromide on cottonseed out of a concern with a shortage of domestically-grown cottonseed. These commenters stressed that “cottonseed is a uniquely superior feed for dairy cattle because it contains high concentrations of protein, energy (or fat), and fiber; is highly digestible; and has proven to increase milk production. The commenters argued that alternative feeds are not “equivalent substitutes” because they do not contain a similar mix of these components and because they are generally more expensive.

The other two comments were adverse to EPA’s proposed action. A comment from one anonymous individual objected to the establishment of the tolerance due to the toxic nature of methyl bromide and due to potential effects on the environment. EPA has determined, however, that there would be no human dietary exposure from the use of methyl bromide to fumigate cottonseed. In addition, the safety standard for approving tolerances under section 408 of the FFDCA focuses on potential harm to human health. Environmental and non-target species considerations are outside of the scope of this rule.

The second comment from another individual raised several issues. EPA is responding to these issues by topic. First, the individual argues that EPA should, in

collaboration with the United States Department of Agriculture (USDA), establish the necessity of cottonseed as feed for cattle by analyzing the supply and demand of cottonseed and available alternatives prior to approving a methyl bromide pesticide tolerance. The commenter also asserts that EPA implies that cottonseed is the only dairy cattle feed available. EPA's response to this concern is twofold. First, and most important, EPA's discussion of the decreased availability of cottonseed in the proposed rule was included only for the purpose of explaining the context of the Agency action. It did not provide the legal basis for the proposed tolerance. The legal standard for the establishment of a tolerance is whether the tolerance is safe. 21 U.S.C. 346a(b)(2)(A)(i). The degree of shortage of cottonseed does not affect this safety determination. Thus, both this comment and the comments from the trade association and dairy expert do not address the legal basis for establishing the proposed methyl bromide tolerance on cottonseed. Second, while not relevant to the ultimate decision on safety, EPA's statements regarding the current shortage of cottonseed were accurate. According to USDA, drought conditions in Texas have reduced cotton production by 13% between the 2010/2011 and 2011/2012 seasons. In 2011, the average U.S. yield of cotton per harvested acre was the lowest it had been since 2003. Moreover, as noted in the proposal and as supported by the commenters familiar with the dairy industry, cottonseed is an important source of protein, energy, and fiber in the dairy cattle diet. It generally comprises up to 15 percent of the daily dietary dry matter intake of lactating dairy cattle.

The commenter questions two decisions and assumptions made by EPA in its decision to establish a tolerance: The use of fumigation trials on tree nuts as a surrogate for cottonseed and the assumption that methyl bromide would undergo chemical

reactions in the digestive system of dairy cattle. The Agency believes that nuts are an adequate surrogate in the case of methyl bromide commodity fumigation. In controlled trials with numerous commodities, nuts had the highest residues of any commodity. Studies with other small seeds such as poppy seeds and sesame seeds showed residues of 35 ppm, in contrast to the nuts where a maximum residue of 138 ppm was observed. To be protective, the Agency chose to translate from nuts to cottonseed, since they both contain oils. While the Agency does not have specific studies on the metabolism of methyl bromide in cattle, oral metabolism studies in rats have indicated methyl bromide undergoes chemical transformations in the digestive system to compounds that are thought to be less toxic. Ruminants such as cattle have complex digestive systems with four compartments, including a fermentation chamber. Therefore, given the complexity of the ruminant digestive system, there is considerably more opportunity for digestion and detoxification of a simple molecule such as methyl bromide in cattle as compared to rats. Finally, the commenter also claims that EPA failed to consider the impact of methyl bromide pesticide levels in cottonseed used as feed on the health of livestock. EPA expects methyl bromide exposure to cattle to be very low. Cottonseed is very unlikely to comprise more than 15% of the dairy cattle diet and cottonseed and residues of methyl bromide in all other potential feed items are much lower than the levels anticipated in cottonseed. Further, residues of methyl bromide in the cottonseed will be very low, as the residues will largely dissipate after fumigation, especially given the time needed to ship cottonseed to the United States. For commodity fumigations with methyl bromide the Agency generally sets tolerances based on residue levels 24 hours after completion of fumigation. Commodities such as nuts and cottonseed are stored for much longer than 24

hours before they are distributed for consumption. Controlled trials with nuts as well as other commodities indicate that residues dissipate considerably with time. For example, residues in nuts dissipated to residues ranging from <0.1 to 11 ppm after only 1 week of storage. Mammalian oral toxicity studies available to the Agency indicate that much higher concentrations of methyl bromide in the diet would be needed to elicit any sort of toxic effect (the maximum reasonable dietary burden for dairy cattle is approximately 20 ppm (assuming upper bound residues), and the no-observed effect level in long-term oral toxicity studies in rats is approximately 50 ppm).

The commenter asserts that approving the use of methyl bromide fumigation on cottonseed imports will increase occupational exposure to methyl bromide and requests that EPA weigh the risks of occupational exposure against the benefits of imported cottonseed. However, under the existing legal framework provided by section 408 of the FFDCA EPA is authorized to establish pesticide tolerances or exemptions where it has been demonstrated that the tolerance meets the safety standard imposed by that statute. In making this determination, EPA is specifically prohibited from considering occupational exposure to a pesticide. 21 U.S.C. 346a(b)(2)(D)(vi). If an applicant sought to register methyl bromide for use in the United States, the issue of risks from occupational exposure would be considered by EPA in making a determination on registration of such a use under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 et seq.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate analytical method, the head-space procedure of King et al. is available for enforcement of methyl bromide tolerances. Samples are blended with water at high speed in airtight jars for 5 minutes. After 15 minutes, the partitioned gas phase is sampled and analyzed by gas chromatography with electron capture detection (GC/EC). See the February 22, 2002, Residue Chemistry Chapter for the methyl bromide RED available in Docket EPA-HQ-OPP-2005-0123.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for methyl bromide on cottonseed.

V. Conclusion

Based on the information, analysis, and conclusions in the April 6, 2012 proposal (77 FR 20752) (FRL-9345-1), as well as the consideration of public comments discussed

herein, a tolerance is established for residues of methyl bromide in or on cottonseed at 150 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) on EPA's own initiative. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Pursuant to the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that this rule will not have significant negative economic impact on a substantial number of small entities. Establishing a pesticide tolerance or an exemption from the requirement of a pesticide tolerance is, in effect, the removal of a regulatory restriction on pesticide residues in food and thus such an action will not have any negative economic impact on any entities, including small entities.

This final rule directly regulates growers, food processors, food handlers, and

food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United

States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 7, 2012.

Steven Bradbury,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Add §180.124 to subpart C to read as follows:

§ 180.124 Methyl Bromide; tolerances for residues.

(a) *General.* A tolerance is established for residues of the fumigant methyl bromide, including metabolites and degradates, in or on the commodity in the table below. Compliance with the tolerance level specified below is to be determined by measuring only methyl bromide.

Commodity	Parts per million
Cotton, undelinted seed	150

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

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06/13/2012]